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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/816,376	04/02/2004	Claude Singer	1662/492021	9531
26646 7590 06/09/2008 KENYON & KENYON LLP ONE BROADWAY NEW YORK, NY 10004				
EXAMINER PESELEV, ELLI				
ART UNIT 1623		PAPER NUMBER		
MAIL DATE 06/09/2008		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/816,376

**Applicant(s)**

SINGER ET AL.

**Examiner**

Ellie Peseelev

**Art Unit**

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-946)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-7 are directed to a "non-hygroscopic" compound.. However, in the specification, the compound is defined as being less hygroscopic. Further, Figure 1 shows an ethanolate crystal taking up water. Therefore, it is confusing whether the claimed compounds are supposed to be non-hygroscopic or less hygroscopic.

Claim 7 is directed to one specific powder diffraction pattern which should relate to one structure. However, the claim also reads on a compound "having ethanol content of about 1.5% to about 3%." Thus it is no clear whether claim 1 is limited to a specific compound or a mixture of compounds i.e. the metes and bounds of the claimed invention are not clearly defined in claim 7.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by the Chinese Patent 1161971A.

The Chinese patent discloses crystalline non-dihydrate azithromycin prepared from a mixture of ethanol and acetone in water (Example 2). Since the claimed azithromycin ethanolate does not exclude the presence of acetone, the claimed compound reads on the reference's compound.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Chinese Patent No. 1161971A.

The Chinese Patent discloses crystalline azithromycin non-dihydrate prepared from a mixture of ethanol and acetone in water (Example 2). However, in claim 6 of the Chinese Patent it is disclosed that said crystalline azithromycin can also be prepared from ethanol or acetone in water. Therefore, the claimed crystalline azithromycin ethanolate would have been prima facie obvious from the teaching by the Chinese

Patent that said azithromycin can also be prepared from the ethanol and water in the absence of acetone.

Applicant's arguments filed February 4, 2008 have been fully considered but they are not persuasive.

Applicant contends that the Chinese Patent states that its invention is a crystalline form of azithromycin that is not a hydrate and describes only one crystalline form of azithromycin which cannot contain an organic solvate in its unit cell. Applicant further contends that Example 1 uses only acetone as a solvent and therefore cannot result in ethanolate of azithromycin being made. These arguments have not been found persuasive because Example 2 of the Chinese Patent discloses crystallizing azithromycin from a mixture of ethanol and acetone. Applicant has not provided any evidence in verified form that the claimed compound cannot be formed by the process disclosed in Example 2 of the Chinese Patent. The Declaration filed February 4, 2008 has been considered but has not been found persuasive. The declaration states that since the crystalline azithromycin in Example 1 cannot be ethanolate of azithromycin, the crystalline azithromycin in Example 2 cannot be ethanolate of azithromycin. However, no data or reasons to support statement have been presented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev  
/Elli Peselev/  
Primary Examiner, Art Unit 1623